September 25, 2017

Dr. Francis Collins
Director, National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Dear Dr. Collins:

We are writing to you in our capacities as the chairs of NIH study sections charged with the review of grant applications involving basic research on human subjects. We wish to add our voices to the many others that have already signaled opposition to the expansion of the definition of a clinical trial proposed by NIH's office of extra-mural research, and which is currently scheduled to take effect January 25th 2018. As currently formulated, and even after incorporating revisions based on the input of the scientific community, the expanded definition will encompass much of the basic research conducted in cognitive neuroscience, psychology, education and allied fields. As others have already noted (e.g. http://ipetitions.com/petition/open-letter-nih-collins), this will have a number of serious consequences that will negatively impact scientific progress and the scientific community. In particular, it will have a chilling effect on scientific innovation, add substantially to the administrative burden of scientists and their institutions, and restrict access to funding opportunities and mechanisms.

Our understanding is that the goal of the expanded definition is to enhance the transparency of research supported by the NIH, and to hold grant holders to a higher standard of accountability than hitherto. We fully recognize the need to ensure that publicly funded research is conducted according to the highest scientific standards, and that the results of this research are made available in a timely manner. In addition, we are supportive of the idea that additional measures could and should be taken by NIH to achieve these goals. We are strongly of the opinion however that these goals should be not be pursued by re-defining basic research on human subjects so that much of it falls under the aegis of an existing but inappropriate mechanism.

As has already been noted in the many comments that they have attracted, the examples offered by NIH in an effort to clarify the proposed new policy (https://grants.nih.gov/policy/clinical-trials/case-studies.htm) contain several problematic issues and, arguably, contradictions. We focus on only one issue here, namely, the proposal that an experiment designed to manipulate 'cognitive performance' (such as that described in case study 18c) should be defined as a clinical trial *even when the manipulation is not intended to have an effect on behavior and neural activity beyond the confines of the experiment itself.* By this definition, virtually all experimental studies in cognitive neuroscience and related fields that are reviewed by our study sections would be classified as clinical trials, despite having no immediate health-related implications, no lasting impact on cognitive or neural function, and having been conducted for the purpose of advancing knowledge about the relationship between brain and behavior. It is primarily for this reason that we are convinced that the updates and revisions to the case studies that NIH has made in response to the well-founded objections of many in the scientific community do ***not*** address the fundamental problem with the revised clinical trials definition, i.e., that it conflates basic research that uses experimental manipulations ("interventions") to affect behavioral and neural outcomes for the purpose of testing theoretical ideas and uncovering basic mechanisms with actual clinical trials research that examines interventions for the purpose of evaluating their efficacy in affecting health-related outcomes.

We respectfully request that you and your colleagues re-consider the proposed policy, and that its implementation be delayed until this and other problematic issues have been fully considered. We reiterate that we strongly support measures to improve the transparency and rigor of publicly funded biomedical research. We believe however that in the case of basic research with human subjects, these aims would be best served by the development of a mechanism that has been formulated in collaboration with the broad scientific community that it will impact.

Sincerely

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cc. Dr. Michael Lauer